K112557

JAN - 5 2012

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Stryker Universal Neuro 3 System
Common Name:	Neuro Plating System
Classification Name and Reference:	Preformed alterable cranioplasty plate 21 CFR §882.5320 Burr hole cover 21 CFR §882.5250 Cranioplasty plate fastener 21 CFR §882.5360
Proposed Regulatory Class:	Class II
Product Codes:	GWO – Preformed alterable cranioplasty plate GXR – Burr hole cover HBW – Cranioplasty plate fastener
For Information contact:	Rob Yamashita Sr. Regulatory Compliance Analyst Stryker Craniomaxillofacial 750 Trade Centre Way, Suite 200 Portage, MI 49002 Phone: (269) 389-4258 / Fax: (269) 329-2235 rob.yamashita@stryker.com
Date Prepared:	September 1, 2011

Indications for Use / Intended Use

The Stryker Universal Neuro 3 System is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).

Contraindications

The Stryker Universal Neuro 3 System is contraindicated for the following:

- Use of plates in non-reducible and unstable fractures
- Patients with active local infections
- Patients with metal allergies and foreign body sensitivity

- Potentially non-compliant patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions
- Patients with limited blood supply to, or insufficient quality of, bone
- Use of products in cases where the fixation of the products could result in their peripheral edge coming into contact with the dura mater
- Screws coming in contact with the dura mater
- Use of implants adjacent to developing paranasal sinuses

Technological Characteristics

The Stryker Universal Neuro 3 System is designed for a wide selection of solutions for cranial fixation. It consists of an implant module (a storage module that contains various versions and shapes of plates and screws) for the respective anatomical and indicated areas.

The low profile plates of the Stryker Universal Neuro 3 System provide rigid fixation of cranial flaps with decreased palpability. There is a comprehensive selection of burr hole covers, straight plates, gap plates, 3D-plates, shunt plates, and box plates to provide many fixation options. The malleable plates can be easily contoured by hand without instruments. The pre-shaped skull-base plates provide covers for standard craniectomies, obviating the need to cut or trim mesh.

Performance Data

Materials used for the Stryker Universal Neuro 3 System are the same as the predicate devices. This includes all three product codes (GWO, GXR and HBW). The titanium materials used for manufacturing of the Stryker Universal Neuro 3 implants are rated to be biocompatible according to ISO 10993-1. Cytotoxicity testing was performed according to ISO 10993-1, 10993-5, 10993-12, and 10993-18. The corrosion resistance of all Neuro 3 screws, plates and meshes were demonstrated.

The bending stability of the Universal Neuro 3 plates (product code GWO) and burr hole covers (product code GXR) were tested by following ASTM F 382-99. The Lerch test was passed by all plates.

For the screws (product code HBW), the testing was performed via ASTM F 543 – Standard Specification and Test Methods for Metallic Medical Bone Screws, 2007. Torque, depth and angle were measured. The screws passed the automated insertion test.

Additionally, we tested the fixation stability of our screws with pull out safety testing and the retention force between the screw and the screwdriver blade also utilizing ASTM F 543. All acceptance criteria were met.

Substantial Equivalence

The Stryker Universal Neuro 3 System has been verified and validated according to Stryker procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by Stryker in this 510(k) application was found to be substantially equivalent with these predicate devices:

- Stryker Universal Neuro 2 System (Stryker, K031659)
- Stryker Micro Dynamic Mesh (Stryker, K983528)
- Synthes Neuro Plate and Screw System (Synthes, K022012)
- KLS-Martin Micro Osteosynthesis System (KLS-Martin, K944561/K944565)

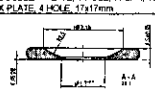
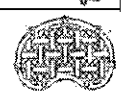
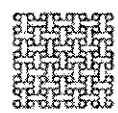
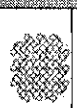
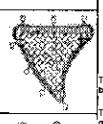
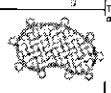
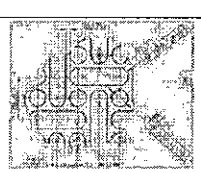
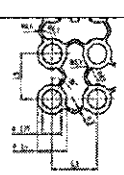
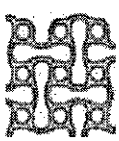
The Stryker Universal Neuro 3 System, as stated above, consists of devices with three product codes: GWO (plates), GXR (burr hole covers), and HBW (screws). It has the same material composition and operating principles as its predicates mentioned above. The intended use is similar to the predicate systems with the only difference being the inclusion of adolescent usc. Further, there may be slight differences in dimensions and shapes between the Stryker Universal Neuro 3 System and the predicate devices; however, the information provided in this 510(k) proves substantial equivalence to the predicate devices.

Specifically speaking, our Universal Neuro 3 burr hole covers and screws are substantially equivalent to Stryker Universal Neuro 2 System (K031659) and

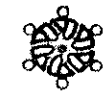
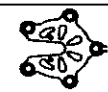
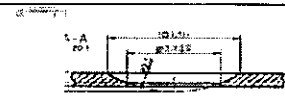
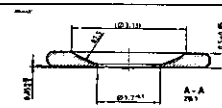
Synthes Neuro Plate and Screw System (K022012). Our Universal Neuro 3 plates are substantially equivalent to the same two predicates named above (K031659 and K022012) plus Stryker Micro Dynamic Mesh (K983528). Also, we included the KLS-Martin Micro Osteosynthesis System (K944561/K944565) as a predicate because of its indicated pediatric use.

Below are three tables that outline our Universal Neuro 3 substantial equivalence.

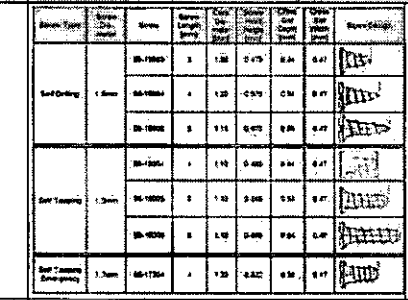
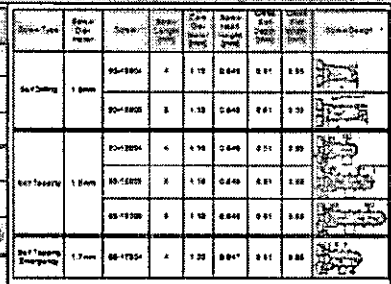
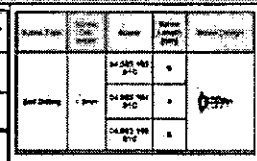
SUBSTANTIAL EQUIVALENCE TABLE: PLATES (Product Code GWO)

Device	Subject Device	Predicate Device	Predicate Device	Subject / Predicate
-	Universal Neuro III	Universal Neuro II	Synthes Matrix Neuro	-
Part Numbers				
-	53-34164 STRAIGHT PLATE, 16 HOLE 53-34804 STRAIGHT PLATE, 8 HOLE 53-34406 STRAIGHT PLATE, 4 HOLE W/BAR 53-34212 2 HOLE, RIGID, 12mm BAR 53-34212 2 HOLE, W/TAB, 12mm BAR 53-34216 2 HOLE, 16mm BAR 53-34228 BOX PLATE, SMALL 53-34230 BOX PLATE, LARGE, W/TAB 53-34240 BOX PLATE, LARGE 53-34300 RECTANGLE PLATE * 53-34612 GAP PLATE, 6 HOLE, SMALL 53-34622 GAP PLATE, 6 HOLE, LARGE 53-34608 DOUBLE-Y PLATE, 6-HOLE, W/BAR 53-34630 X PLATE, 4 HOLE 53-00362 MESH PLATE ROUND, SMALL 53-00364 MESH PLATE ROUND, MEDIUM 53-00466 MESH PLATE ROUND, LARGE 53-00342 TRANSLABYRINTHINE PLATE, SMALL 53-00346 TRANSLABYRINTHINE PLATE, LARGE 53-00324 TEMPORAL PLATE, MEDIUM 53-00382 SUBOCCIPITAL PLATE, SMALL 53-00486 SUBOCCIPITAL PLATE, LARGE	53-05164 STRAIGHT PLATE, 16 HOLE 53-05804 STRAIGHT PLATE, 8 53-05406 STRAIGHT PLATE, 4 HOLE W/BAR 53-06212 2 HOLE, RIGID, 12mm BAR 53-06212 2 HOLE, W/TAB, 12mm BAR 53-05216 2 HOLE, 16mm BAR 53-05228 BOX PLATE, SMALL 53-05230 BOX PLATE, LARGE, W/TAB 53-05240 BOX PLATE, LARGE 53-05612 GAP PLATE, 6 HOLE, SMALL 53-05622 GAP PLATE, 6 HOLE LARGE 53-05608 DOUBLE-Y PLATE 6-HOLE, W/BAR 53-05630 X PLATE, 4 HOLE 54-00344 Dynamic mesh 40x40x0.3mm 54-00346 Dynamic mesh 90x90x0.3mm 54-00345 Dynamic mesh 120x120x0.3mm 54-00645 Dynamic mesh 40x40x0.6mm 54-00646 Dynamic mesh 90x90x0.6mm 54-00647 Dynamic mesh 120x120x0.6mm	04.503.072 Adaption Plate, 20 holes 04.503.071 Adaption Plate, 7 holes 04.503.070 Adaption Plate, 5 holes 04.503.062 Straight Plate, 2 holes, 12mm 04.503.063 Cranial Plate, straight, with centre space, 12 mm, 4 holes 04.503.065 Frame Plate, square, 4 holes, 14x14 mm 04.503.066 Frame Plate, square, 4 holes, 16x16 mm 04.503.073 Frame Plate, rectangular, 4 holes, 10x16 mm 04.503.074 Strut Plate, 2x3 holes, 14x24 mm 04.503.075 Strut Plate, 2x4 holes, 14x34 mm 04.503.068 Double-Y-Plate, 6 holes, length 18 mm 04.503.069 Double-Y-Plate, 6 holes, length 21 mm 04.503.064 X-Plate, 4 holes 04.503.090 Circular, 30x0.4mm, malleable 04.503.091 Circular, 70x0.4mm, malleable 04.503.092 Circular, 100x0.4mm, malleable 04.503.093 Circular, 30x0.4mm, rigid 04.503.094 Circular, 70x0.4mm, rigid 04.503.095 Circular, 100x0.4mm, rigid 04.503.096 Mastoid Plate, small 04.503.097 Mastoid Plate, medium 04.503.098 Mastoid Plate, large 04.503.057 Temporal Mesh Plate, contourable, 0.4mm 04.503.086 Crescent-shaped, small, 0.4mm, malleable 04.503.087 Crescent-shaped, large, 0.4mm, malleable 04.503.088 Crescent-shaped, small, 0.4mm, rigid 04.503.089 Crescent-shaped, large, 0.4mm, rigid	n/a
Manufacturer				
Environment	Stryker Leibinger GmbH & Co. KG, Facility in Joseph-Lang-Str. 22, 78570 Muehlheim an der Donau, GER	Stryker Leibinger GmbH & Co. KG, Facility in Joseph-Lang-Str. 22, 78570 Muehlheim an der Donau, GER	Synthes (USA), 1101 Synthes Avenue, Monument, CO 80132	For Universal Neuro II: Equivalent manufacturer (Stryker/ Stetten) on the equivalent machines using the equivalent machine environment
510(k)				
-	see to new 510k number	K051658, K963528	K022012	n/a
Intended Use				
Indications for use	The Stryker® Universal Neuro III implant system is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher)	The Stryker Leibinger Universal Neuro System is a low profile plate and screw system intended for osteotomy, craniotomy stabilization and rigid fixation of craniofacial fractures and reconstruction in non-load bearing areas.	The Synthes Matrix Neuro Plate and screw System is intended for use as selective trauma of the midface and craniofacial skeleton, craniofacial surgery: reconstructive procedures, and selective orthognatic surgery of the maxilla and chin.	The subjected device is intended to be used in cranial areas which are similar to the predicates but it is limited to non-load bearing cranial indications only, whereas the Synthes predicate indications cover facial/orbital or mandibular sites as well. Additionally the subject is intended to be used in adolescents and adults whereas the predicates have no limitation to this
Application Area	Neuro (Cranial)	Craniofacial	Neuro (Cranial), Midface, Maxilla & Chin	For Universal Neuro II: Equivalent application area compared to Universal Neuro III For Synthes: Enhanced application area including the one of Universal Neuro III
Material				
-	Commercially Pure Titanium, Grade II and IV	Commercially Pure Titanium, Grade II and IV	Commercially Pure Titanium	Equivalent material, therefore all plates are equal in regard to the mechanical and chemical properties of their material
Design Plates				
Size	Straight Plates: 53-34164 STRAIGHT PLATE, 16 HOLE, 85mm 53-34804 STRAIGHT PLATE, 8 HOLE, 33mm 53-34406 STRAIGHT PLATE, 4 HOLE W/BAR, 19mm 53-34212 2 HOLE, RIGID, 12mm BAR 53-34212 2 HOLE, W/TAB, 12mm BAR 53-34216 2 HOLE, 16mm BAR Rectangular Plates: 53-34228 BOX PLATE, SMALL, 12x12mm 53-34230 BOX PLATE, LARGE, W/TAB, 16x16mm 53-34240 BOX PLATE, LARGE, 16x16mm 53-34300 RECTANGLE PLATE, 12x16mm 53-34612 GAP PLATE, 6 HOLE, SMALL, 14x26mm 53-34622 GAP PLATE, 6 HOLE, LARGE, 14x46mm X & Y Plates: 53-34608 DOUBLE-Y PLATE, 6-HOLE, W/BAR, 11x19mm 53-34630 X PLATE, 4 HOLE, 17x17mm	53-05164 STRAIGHT PLATE, 16 HOLE, 85mm 53-05804 STRAIGHT PLATE, 8, 33mm 53-05406 STRAIGHT PLATE, 4 HOLE W/BAR, 19mm 53-06212 2 HOLE, RIGID, 12mm BAR 53-05212 2 HOLE, W/TAB, 12mm BAR 53-05216 2 HOLE, 16mm BAR 53-05228 BOX PLATE, SMALL, 12x12mm 53-05230 BOX PLATE, LARGE W/TAB, 16x16mm 53-05240 BOX PLATE, LARGE, 16x16mm 53-05612 GAP PLATE, 6 HOLE, SMALL, 14x28mm 53-05612 GAP PLATE, 6 HOLE, SMALL, 14x28mm 53-05608 DOUBLE-Y PLATE, 6-HOLE, W/BAR, 10x18mm 53-05630 X PLATE, 4 HOLE, 17x17mm	04.503.072 Adaption Plate, 20 holes 04.503.071 Adaption Plate, 7 holes 04.503.070 Adaption Plate, 5 holes 04.503.062 Straight Plate, 2 holes, 12mm 04.503.063 Cranial Plate, straight, with centre space, 12 mm, 4 holes 04.503.065 Frame Plate, square, 4 holes, 14x14 mm 04.503.066 Frame Plate, square, 4 holes, 16x16 mm 04.503.073 Frame Plate, rectangular, 4 holes, 10x16 mm 04.503.074 Strut Plate, 2x3 holes, 14x24 mm 04.503.075 Strut Plate, 2x4 holes, 14x34 mm 04.503.068 Double-Y-Plate, 6 holes, length 18 mm 04.503.069 Double-Y-Plate, 6 holes, length 21 mm 04.503.064 X-Plate, 4 holes	The shape of the Universal Neuro III subject devices is equivalent to the range offered by both predicate devises.
Countersink			n/a	The shape of the countersink is widened by means of the diameter at the lower opening. Due to the Universal Neuro III screw head diameter of 2.7mm the screw is not endangered to fall through the plate hole
Thickness	0.6mm (1 "rigid" plate) and 0.4mm (all others)	0.6mm (1 "rigid" plate) and 0.5mm (all others)	0.4mm	The thickness of the 0.4mm subject devices is equivalent to the Synthe predicate devices. The 0.6mm subject device is equivalent to the 0.6mm Universal Neuro II device
Surface treatment	Type III Anodization	Type III Anodization	n/a	Equivalent surface treatment of Universal Neuro I and III devices
Design Skull Base Plates				
Size	Round Mesh Plates Round shaped 53-00362 Ø41.5mmx0.3mm 53-00364 Ø46.6mmx0.3mm 53-00466 Ø57.6mmx0.4mm  Translabyrinthine Plates Triangular shaped 53-00347: 54.9x51.9x0.3mm 53-00346: 60.3x59.9x0.3mm  Temporal Plate Bean shape 53-00324 47x29x0.3mm  Subocciptial Plates: Trapezoid shaped 53-00382: 61.8x32.1x0.3mm 53-00486: 65.4x41.5x0.4mm 	54-00344: Dynamic mesh 40x40x0.3mm 54-00346: Dynamic mesh 90x90x0.3mm 54-00345: Dynamic mesh 120x120x0.3mm 54-00645: Dynamic mesh 40x40x0.6mm 54-00646: Dynamic mesh 90x90x0.6mm 54-00647: Dynamic mesh 120x120x0.6mm 	04.503.090 Circular, 30x0.4mm, malleable 04.503.091 Circular, 70x0.4mm, malleable 04.503.092 Circular, 100x0.4mm, malleable 04.503.093 Circular, 30x0.4mm, rigid 04.503.094 Circular, 70x0.4mm, rigid 04.503.095 Circular, 100x0.4mm, rigid  04.503.096 Mastoid Plate, small 04.503.097 Mastoid Plate, medium 04.503.098 Mastoid Plate, large  04.503.057 Temporal Mesh Plate, contourable, 0.4mm  04.503.086 Crescent-shaped, small, 0.4mm, malleable 04.503.087 Crescent-shaped, large, 0.4mm, malleable 04.503.088 Crescent-shaped, small, 0.4mm, rigid 04.503.089 Crescent-shaped, large, 0.4mm, rigid 	The shape of the Universal Neuro III Skull Base subject devices is equivalent to the ones offered by the predicate devises from Synthes. The outer dimensions of the Universal Neuro III Skull Base subject devices is within the range offered by both predicate devices
Internal Mesh Pattern				The pattern of the subject devices as well as all predicate devices is equivalent characterized by fixation holes surrounded by connecting bars The pattern holes are of equivalent dimensions between the Universal Neuro III subject devices and the Universal Neuro II predicate devices. The hole connecting bars of the Universal Neuro III subject devices are wider than the ones of the Universal Neuro II predicate devices offering more stability
Thickness	3.3mm and 0.4mm	0.3mm and 0.6mm	0.4mm and 0.6mm	The thickness of the Universal Neuro III Skull Base subject devices is within the range offered by both predicate devices
Surface treatment	Type III Anodization	Type III Anodization	-	Equivalent surface treatment of Universal Neuro II and III devices
Operation / Principle				
Surgical Technique/Site Preparation	see intended use	see intended use	see intended use	see intended use

SUBSTANTIAL EQUIVALENCE TABLE: BURR HOLE COVERS (Product Code GXR)

Device		Subject	Predicate	Predicate	Similarities / Differences
-		Universal Neuro III	Universal Neuro II	Synthes Matrix Neuro	n/a
Part Number					
-		53-34507: 7mm Burr Hole Cover 53-34510: 10mm Burr Hole Cover 53-34514: 14mm Burr Hole Cover 53-34520: 20mm Burr Hole Cover 53-34524: 24mm Burr Hole Cover 53-34614 : 14mm Shunt 53-34620 : 20mm Shunt	53-05507: 7mm Burr Hole Cover 53-05510: 10mm Burr Hole Cover 53-05514: 14mm Burr Hole Cover 53-05520: 20mm Burr Hole Cover	04.503.021: 12mm Burr Hole Cover 04.503.022: 15mm Burr Hole Cover 04.503.023: 17mm Burr Hole Covert 04.503.024: 24mm Burr Hole Cover 04.503.026: 12mm Shunt 04.503.027: 15mm Shunt 04.503.028: 17mm Shunt 04.503.029: 24mm Shunt	n/a
Manufacturer					
Environment		Stryker Leibinger GmbH & Co. KG, Facility in Joseph-Lang-Str. 22, 78570 Muehlheim an der Donau, GER	Stryker Leibinger GmbH & Co. KG, Facility in Joseph-Lang-Str. 22, 78570 Muehlheim an der Donau, GER	Synthes (USA), 1101 Synthes Avenue, Monument, CO 80132	For Universal Neuro II: Equivalent manufacturer (Stryker/ Stetten) on the equivalent machines using the equivalent machine environment.
510(k)					
		acc to new 510k number	K031659	K022012	n/a
Intended Use					
Indications for use		The Stryker® Universal Neuro III implant system is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).	The Stryker Leibinger Universal Neuro System is a low-profile plate and screw system intended for osteotomy, craniotomy, stabilization and rigid fixation of craniofacial fractures and reconstruction in non-load bearing areas.	The Synthes Matrix Neuro Plate and screw System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognatic surgery of the maxilla and chin.	The subjected device is intended to be used in cranial areas which are similar to the predicates. But it is limited to non-load bearing cranial indications only, whereas the Synthes predicate indications cover facial/orbital or mandibular sites as well. Additionally the subject is intended to be used in adolescents and adults whereas the predicates have no limitation to this.
Application Area		Neuro (Cranial)	Craniofacial	Neuro (Cranial), Midface, Maxilla & Chin	For Universal Neuro II: Equivalent application area compared to Universal Neuro III For Synthes: Enhanced application area including the one of Universal Neuro III
Material					
-		Commercially Pure Titanium	Commercially Pure Titanium	Commercially Pure Titanium	Equivant material, therefore all plates are equal in regard to the mechanical and chemical properties of their material.
Design					
Design	Burrhole Cover	53-34507: 7mm 53-34510: 10mm 53-34514: 14mm 53-34520: 20mm 53-34524: 24mm 	53-05507: 7mm 53-05510: 10mm 53-05514: 14mm 53-05520: 20mm 	04.503.021: 12mm 04.503.022: 15mm 04.503.023: 17mm 04.503.024: 24mm 	The subjected devices are of equivalent choice of sizes as available for the predicate devices. The number for countersinks for screw insertion of the subject devices are equivalent to the ones of the Synthes predicte devices.
	Shunt Plates	53-34614 : 14mm 53-34620 : 20mm 	n/a	04.503.026: 12mm 04.503.027: 15mm 04.503.028: 17mm 04.503.029: 24mm 	The subjected devices are of equivalent choice of sizes as available for the predicate devices. The number for countersinks for screw insertion of the subject devices are equivalent to the ones of the Synthes predicte devices.
Countersink				n/a	The shape of the countersink is widened by means of the diameter at the lower opening. Due to the Universal Neuro III screw head diameter of 2,7mm the screw is not endangered to fall through the plate hole.
Thickness		0.4mm	0.5mm	0.4mm	The thickness of the subject devices is equivalent to the Synthe spradicate devices.
Surface treatment		Type III Anodization	Type III Anodization	n/a	Equivalent surface treatment of Universal Neuro II and III devices.
Operational Principles					
Surgical Technique/Site Preparation		see intended use	see intended use	see intended use	see intended use

SUBSTANTIAL EQUIVALENCE TABLE: SCREWS (Product Code HBW)

Device	Subject	Predicate		Similarities / Differences
-	Stryker Universal Neuro III	Stryker Universal Neuro II	Synthes Matrix Neuro	n/a
Part Number				
-	58-15903 1.5x3mm self drilling 58-15904 1.5x4mm self drilling 58-15905 1.5x5mm self drilling 58-15004 1.5x4mm self tapping 58-15005 1.5x5mm self tapping 58-15006 1.5x6mm self tapping 58-17304 1.7x4mm self tapping emergency	50-15904 1.5x4mm self drilling 50-15905 1.5x5mm self drilling 50-15004 1.5x4mm self tapping 50-15005 1.5x5mm self tapping 50-15006 1.5x6mm self tapping 50-17304 1.7x4mm self tapping emergency	04.503.103.01 1.5x3mm self drilling 04.503.104.01 1.5x4mm self drilling 04.503.105.01 1.5x5mm self drilling	n/a
Manufacturer				
Environment	Stryker Leibinger GmbH & Co. KG, Boetzinger Str. 41, 79111 Freiburg, GER	Stryker Leibinger GmbH & Co. KG, Boetzinger Str. 41, 79111 Freiburg, GER	Synthes (USA), 1101 Synthes Avenue, Monument, CO 80132	For Universal Neuro II: Equivalent manufacturer (Stryker/ Freiburg) on the equivalent machines using the equivalent machine environment compared to Universal Neuro III
510(k)				
-	acc to new 510k number	K031659	K022012	n/a
Intended Use				
Indications for use	The Stryker® Universal Neuro III implant system is intended for reconstruction, stabilization and/or rigid fixation of non load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).	The Stryker Leibinger Universal Neuro System is a low-profile plate and screw system intended for osteotomy, craniotomy, stabilization and rigid fixation of craniofacial fractures and reconstruction in non-load bearing areas.	The Synthes Matrix Neuro Plate and screw System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures, and selective orthognatic surgery of the maxilla and chin.	The subject device is intended to be used in cranial areas which are similar to the predicates. But it is limited to non-load bearing cranial indications only, whereas the Synthes predicate indications cover facial/orbital or mandibular sites as well. Additionally the subject is intended to be used in adolescents and adults whereas the predicates have no limitation to this.
Application Area	Neuro (Cranial)	Craniofacial	Neuro (Cranial), Midface, Maxilla & Chin	For Universal Neuro II: Equivalent application area compared to Universal Neuro III For Synthes: Enhanced application area including the one of Universal Neuro III
Material				
-	Titanium Alloy, Grade V	Titanium Alloy, Grade V	Titanium Alloy	Equivant material, therefore all screws are equal in regard to the mechanical and chemical properties of their material.
Design				
Size				The design features of the screws are: - Head Geometry (outer shape): Reduced screw head heights & decreased cross slot widths and depths compared to Universal Neuro II screws; Verification/Validation testing proved safety of Universal Neuro III design; - Core Diameter: Equivalent core diameter for Universal Neuro II and III self tapping screws and the 5mm self-drilling screws, increased core diameter for Universal Neuro III 3mm and 4mm self drilling screws increasing the screw stability compared to Universal Neuro II; - Length: Equivalent to the predicates except for Universal Neuro III 3mm self drilling screw which is not included in the Universal Neuro II system
Surface treatment	Type II Anodization	Type III Anodization	n/a	For Universal Neuro II: Equivalent surface treatment compared to Universal Neuro III
Operational Principle				
Surgical Technique/Site Preparation	see intended use	see intended use	see intended use	see intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Rob Yamashita
Senior Regulatory Affairs Representative
Stryker Craniomaxillofacial
750 Trade Centre Way, Suite 200
Portage, MI 49002

JAN - 5 2012

Re: K112557
Trade/Device Name: Stryker Universal Neuro 3 System
Regulation Number: 21 CFR 882.5320
Regulation Name: Performed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: December 28, 2011
Received: December 29, 2011

Dear Mr. Yamashita:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K112557

Device Name: Stryker Universal Neuro 3 System

Indications For Use:

The Stryker Universal Neuro 3 System is intended for reconstruction, stabilization and/or rigid fixation of non-load-bearing bony areas subsequent to craniotomy, craniectomy and cranial fractures in adults and adolescents (age 12 and higher).

Contraindications:

The Stryker Universal Neuro 3 System is contraindicated for the following:

- Use of plates in non-reducible and unstable fractures
- Patients with active local infections
- Patients with metal allergies and foreign body sensitivity
- Potentially non-compliant patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions
- Patients with limited blood supply to or insufficient quality of bone
- Use of products in cases where the fixation of the products could result in their peripheral edge coming into contact with the dura mater
- Screws coming in contact with the dura mater
- Use of implants adjacent to developing paranasal sinuses

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112557